Notice of Allowability	Application No.	Applicant(s)	
	09/724,822	LINNIK ET AL.	
	Examiner	Art Unit	
	Celine X Qian Ph.D.	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the amendment filed on 9/7/04*.

2. ☒ The allowed claim(s) is/are *1,3,4,6-10,12,14,15,17-19,33,35-39,65-83,85,86 and 88-110*.

3. ☒ The drawings filed on *17 April 2003* are accepted by the Examiner.

4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 9/7/04
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Applicant's representative Jill Jacobson on 12/8/04.

The application has been amended as follows:

Claim 15. A method of treating SLE in an individual, comprising

(a) assessing before initiation of treatment an apparent equilibrium dissociation constant (K_D') or a functional equivalent thereof for a polynucleotide in a conjugate and an antibody from the individual which specifically binds to double stranded DNA, said conjugate comprising (i) a non-immunogenic valency platform molecule and (ii) two or more polynucleotides which specifically bind to an antibody from the individual which specifically binds to double stranded DNA, said polynucleotides consisting essentially of the double stranded sequence 5'-GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1), wherein the individual is selected to receive the treatment if the K_D' is less than about 0.8 mg IgG per ml; and

(b) administering an effective amount of the conjugate to the selected individual in an amount sufficient to increase the K_D'.

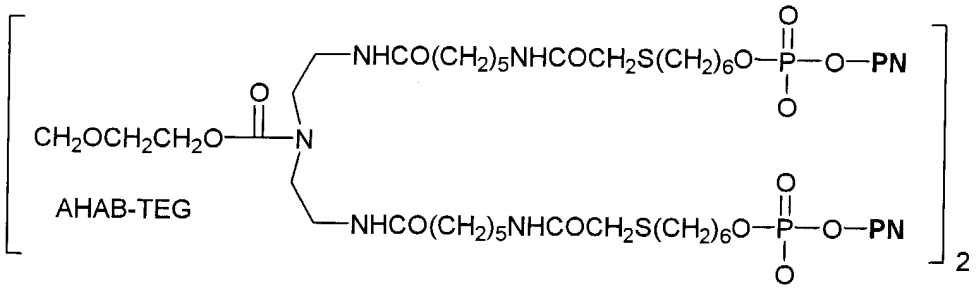
Claim 65. ~~A~~ The method ~~according to~~ of claim 1, wherein said affinity is measured by surface plasmon resonance assay.

Claim 66. ~~A~~ The method ~~according to~~ of claim 1, wherein the polynucleotides comprise the double stranded sequence 5'-GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1).

Claim 67. ~~A~~ The method ~~according to~~ of claim 1, wherein the polynucleotides consist essentially of the double stranded sequence 5'-GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1).

Claim 68. ~~A~~ The method ~~according to~~ of claim 1, wherein the polynucleotides consist of the double stranded sequence 5'-GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1).

Claim 69. ~~A~~ The method ~~according to~~ of claim 1, wherein the platform molecule is



wherein PN is the polynucleotide.

Claim 70. ~~A~~ The method ~~according to~~ of claim 69, wherein the polynucleotides comprise the double stranded sequence 5'-GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1).

Claim 71. ~~A~~ The method ~~according to~~ of claim 69, wherein the polynucleotides consist essentially of the double stranded sequence 5'-GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1).

Claim 72. ~~A~~ The method ~~according to~~ of claim 69, wherein the polynucleotides consist of the double stranded sequence 5'-GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1).

Claim 73. ~~A~~ The method ~~according to~~ of claim 4, wherein the K_D' value is measured by surface plasmon resonance assay.

Claim 74. ~~A~~ The method ~~according to~~ of claim 4, wherein the conjugate comprises four polynucleotides consisting essentially of the double stranded sequence 5'-GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1).

Claim 75. ~~A~~ The method ~~according to~~ of claim 4, wherein the conjugate comprises four polynucleotides consisting of the double stranded sequence 5'-GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1).

Claim 76. ~~A~~ The method ~~according to~~ of claim 12, wherein said antibody affinity is measured by surface plasmon resonance assay.

Claim 77. ~~A~~ The method ~~according to~~ of claim 12, wherein the polynucleotides comprise the double stranded sequence 5'-GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1).

Claim 78. ~~A~~ The method ~~according to~~ of claim 12, wherein the polynucleotides consist essentially of the double stranded sequence 5'-GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1).

Claim 79. ~~A~~ The method ~~according to~~ of claim 12, wherein the polynucleotides consist of the double stranded sequence 5'-GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1).

Claim 80. ~~A~~ The method ~~according to~~ of claim 10, wherein the polynucleotides comprise the double stranded sequence 5'-GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1).

Claim 81. ~~A~~ The method ~~according to~~ of claim 10, wherein the polynucleotides consist essentially of the double stranded sequence 5'-GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1).

Claim 82. ~~A~~ The method ~~according to~~ of claim 10, wherein the polynucleotides consist of the double stranded sequence 5'-GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1).

Claim 83. ~~A~~ The method ~~according to~~ of claim 15, wherein the K_D' value is measured by surface plasmon resonance assay.

Claim 85. ~~A~~ The method ~~according to~~ of claim 15, wherein the conjugate comprises four polynucleotides consisting essentially of the double stranded sequence 5'-GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1).

Claim 86. ~~A~~ The method ~~according to~~ of claim 15, wherein the conjugate comprises four polynucleotides consisting of the double stranded sequence 5'-GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1).

Claim 88. ~~A~~ The method ~~according to~~ of claim 19, wherein the polynucleotides consist essentially of the double stranded sequence 5'- GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1).

Claim 89. ~~A~~ The method ~~according to~~ of claim 19, wherein the polynucleotides consist of the double stranded sequence 5'- GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1).

Claim 90. ~~A~~ The method ~~according to~~ of claim 33, wherein the K_D' value is measured by surface plasmon resonance assay.

Claim 91. ~~A~~ The method ~~according to~~ of claim 33, wherein the conjugate comprises four polynucleotides comprising the double stranded sequence 5'- GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1).

Claim 92. ~~A~~ The method ~~according to~~ of claim 39, wherein the polynucleotides consist of the double stranded sequence 5'- GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1).

Claim 98. ~~A~~ The method ~~according to~~ of claim 1, wherein said polynucleotides comprise single stranded sequences.

Claim 99. ~~A~~ The method ~~according to~~ of claim 1, wherein said polynucleotides comprise double stranded sequences.

Claim 100. ~~A~~ The method ~~according to~~ of claim 3, wherein said double stranded DNA comprises the sequence 5'- GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1).

Claim 101. ~~A~~ The method ~~according to~~ of claim 3, wherein said double stranded DNA consists essentially of the sequence 5'- GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1).

Claim 102. ~~A~~ The method ~~according to~~ of claim 3, wherein said double stranded DNA consists of the sequence 5'- GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1).

Claim 103. ~~A~~ The method ~~according to~~ of claim 12, wherein said polynucleotides comprise single stranded sequences.

Claim 104. ~~A~~ The method ~~according to~~ of claim 12, wherein said polynucleotides comprise double stranded sequences.

Claim 105. ~~A~~ The method ~~according to~~ of claim 14, wherein said double stranded DNA comprises the sequence 5'- GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1).

Claim 106. ~~A~~ The method ~~according to~~ of claim 14, wherein said double stranded DNA consists essentially of the sequence 5'- GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1).

Claim 107. ~~A~~ The method ~~according to~~ of claim 14, wherein said double stranded DNA consists of the sequence 5'- GTGTGTGTGTGTGTGTGTGT-3' (SEQ ID NO:1).

Claim 108. ~~A~~ The method ~~according to~~ of claim 33, wherein said polynucleotides comprise single stranded sequences.

Claim 109. ~~A~~ The method ~~according to~~ of claim 33, wherein said polynucleotides comprise double stranded sequences.

Claim 110. ~~A~~ The method ~~according to~~ of claim 100, wherein the apparent equilibrium dissociation constant (K_D') for the double stranded DNA with respect to the antibody from the individual before or upon initiation of treatment is less than about 0.8 mg IgG per ml, wherein said K_D' value or a functional equivalent thereof is used as a basis for selecting the individual to receive the treatment.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celine X Qian Ph.D. whose telephone number is 571-272-0777. The examiner can normally be reached on 9:30-6:00 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Celine X Qian Ph.D.
Examiner
Art Unit 1636